"OGB Poly Care 4"
Incubator
Instruction Manual

THIS MANUAL HAS BEEN REALIZED
RESPECTING THE ENFORCED NORMS.

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WHITE PAGE

PRESENTATION

Dear customer,

we would like to thank you for choosing our Incubators "OGB Poly Care Line". Ginevri's quality, long experience, safety and easy maintenance will prove to be the best reward for your continuous interest in our products line.

Giorgio Ginevri

GINEVRI s.r.l. – Registered office

Via Giacomo Boni - 00162 Roma

Warnings

Before using the device, all personnel, who will be working with the unit, should read and thoroughly understand this manual.

This manual provides instructions for installation, use and operator maintenance. Ginevri cannot be responsible for the performance of the Incubators *OGB Poly Care Line* if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations in this manual, or effect any repairs with unauthorised components.

Repair should be performed only by qualified service personnel. Technical information is available through your local distributor.

If there is anything you do not understand, please contact your Ginevri's representative for further information.

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Incubator *OGB Poly Care 4*

S/N

"EC" CERTIFICATE

EC CERTIFICATE

Certificate No 747/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

GINEVRI SRL

manages in the factories of:

CECCHINA STAZIONE (RM) - VIA CANCELLIERA 25/D (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

Infant incubators

Transport infant incubators

Infant warmers

Infant heating mattress

Oxygen analyzers

Oxygen tents

Phototherapy lamps in neonatal hyperbilirubinemia

Auxiliary infant warmers

Air compressor for transport incubator

Medical humidifiers

Neonatal Ventilators

series and type refs in the Annex

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AE00087; 10AE00174

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.
Notified Body notified to European Commission under number: 0051.

Date: 2004-04-21
Updated: 2004-10-01
Substitution Date: 2004-04-21

IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2009-04-20 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

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NOTES

1. PRECAUTIONS

1.1 OPERATING PRECAUTIONS

This Instruction Manual must be carefully read and understood by all personnel who install, operate or service the **OGB Poly Care 4** Incubator.
This Incubator should be operated, maintained and repaired in accordance with the instructions contained in this manual.

When use oxygen avoid using alcohol and ether that may cause fire.
Oxygen hoods may increase the noise level inside the incubator.

Slide out the control panel from the base carefully when the heating unit may be still hot.

The heating unit is soundless: internal noise level 45-47dB. Should the noise level increase sensibly, it is advisable to check the unit in order to prevent or limit damages.

Incubator misuse may result in harm to the infant. Incubators should be used only by properly trained personnel as directed by an appropriately qualified attending physician aware of currently known hazards and benefits.

Before using the incubator with patients, the incubator and the accessories should be checked, thoroughly cleaned and disinfected to ensure that equipment is in proper operating condition . See Routine Maintenance instructions.

Direct sun-light or any other external heating sources (like photerapy lamps, radiators) may increase the temperature inside the incubator dangerously. Nevertheless the **OGB Poly Care 4** separate Max Temperature Audio-visual alarm will activate at 40°C

Remove the control panel from the base carefully when the heating unit may be still hot

The incubator should not be used if it fails to function properly. Service should be referred to qualified personnel.

For safety DO NOT leave the infant unattended when the door is open.

To prevent accidental disconnection, secure all patient leads, infusion lines and ventilator tubing to the mattress with sufficient excess length to allow full range height adjustment of the mattress.

When moving the incubator, two persons of sufficient strength are required for adequate control.

1.2 ELECTRICAL PRECAUTIONS.

To ensure grounding reliability, connect the AC Power Cord only to a properly grounded 3 wire hospital grade or hospital use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment.

An electric shock hazard exist within the Controller when the cover is removed. Servicing should be performed only by qualified personnel.

Make sure the building power source is compatible with the electrical specifications shown on the incubator' s label.

1.3 EXPLOSION PRECAUTIONS

Do not use in the presence of flammable anesthetics.

Make sure that oxygen supply to the incubator is turned off and the incubator is disconnected from the oxygen supply when performing cleaning and maintenance procedure; a fire and explosion hazard exists when performing cleaning and/or maintenance procedure in an oxygen – enriched environment.

Keep matches, lighted cigarettes, and all other sources of ignition cut out of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

2. INTRODUCTION

The philosophy that has guided GINEVRI in the design of their products for the last 40 years is ***Maximum Performance***, and ***User Friendliness*** at the same time. This philosophy has conducted to the line of incubators OGB *Poly Care*.

Poly Care control units are microprocessor driven and can control all the parameters necessary to obtain the ideal environment for the premature baby. Depending on the model is possible to monitor and control:

- Temperature (Air, Skin) with proportional heating;
- Humidity, with an integrated sterile humidity generating system;
- Oxygen concentration in the hood or in the head-box;

Data are displayed on big, clear colour displays and the desired parameter values are set trough soft-touch sealed keys arranged in an intuitive and error-free pattern.
Up to 126 incubator can be connected to a networking system and monitored by a remote computer.
The intensive care incubators can be equipped with the revolutionary *Hot-Spot* radiant heater, when this system is fitted the baby skin temperature is maintained constant even with both doors open, thus eliminating the clumsiness of the double wall and the danger of the air curtain.

Technology and materials
The choice of materials and technologies employed is what makes the difference in the new generation of incubators. Hood, base and main components of the *Poly Care* incubators are injection-moulded in Polycarbonate (Lexan).
Poly Care incubators are «unique» for their design, features and manufacturing technologies, on the market it is impossible to find apparatus with all this features at the same time.
The injection-moulding in a single block , the absence of glued junctions and the round shapes improve the air circulation, reduce the internal noise level and allow a radical cleaning and sterilisation. All this features and details guarantee the incubator optimal performance.
To order a spare part from every part of the world what you need is just a fax and a part number.
The technical solutions employed for the *Poly Care* incubators make maintenance and servicing easy and economical. Even the need for specialised service engineers is no longer required. This happens because the mechanical components, manufactured with a moulding process, are all strictly identical and because, thanks to digital electronics, servicing means only changing a board or a probe.
Incubator base, control panel, humidifier, patient tray and *Smooth-Tilt*, are all injection moulded in Polycarbonate (Lexan).
Polycarbonate is unbreakable, high temperature resistant, fire retardant, disinfectants and chemicals resistant.
Thanks to the materials and the technologies employed the apparatus can be completely disassembled without tools in a few minutes.

The hood of *Poly Care* incubators is made in lexan too, this material is, unbreakable, heat resistant (up to 150°C), durable. The single piece injection moulding and, therefore, the absence of joined or glued parts, guarantees hygiene and sterility. For all this reasons Lexan hoods outperform under every aspect traditional acrylic plexiglas hoods.

For an optimal access to the patient the doors on the two sides of the hood can be completely opened and when open, the hood top is still accessible. The hood is equipped with six port-holes provided of dampened opening.

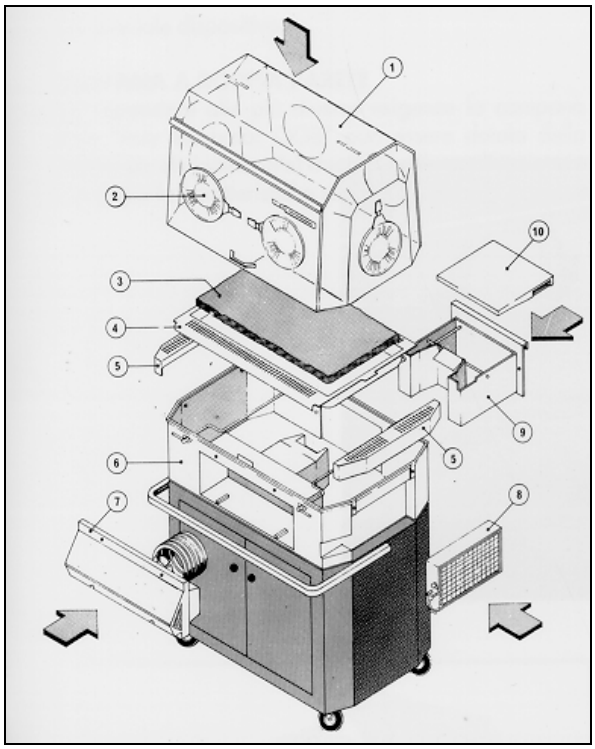
3. GENERAL INSTRUCTIONS

3.1 GENERAL DESCRIPTION

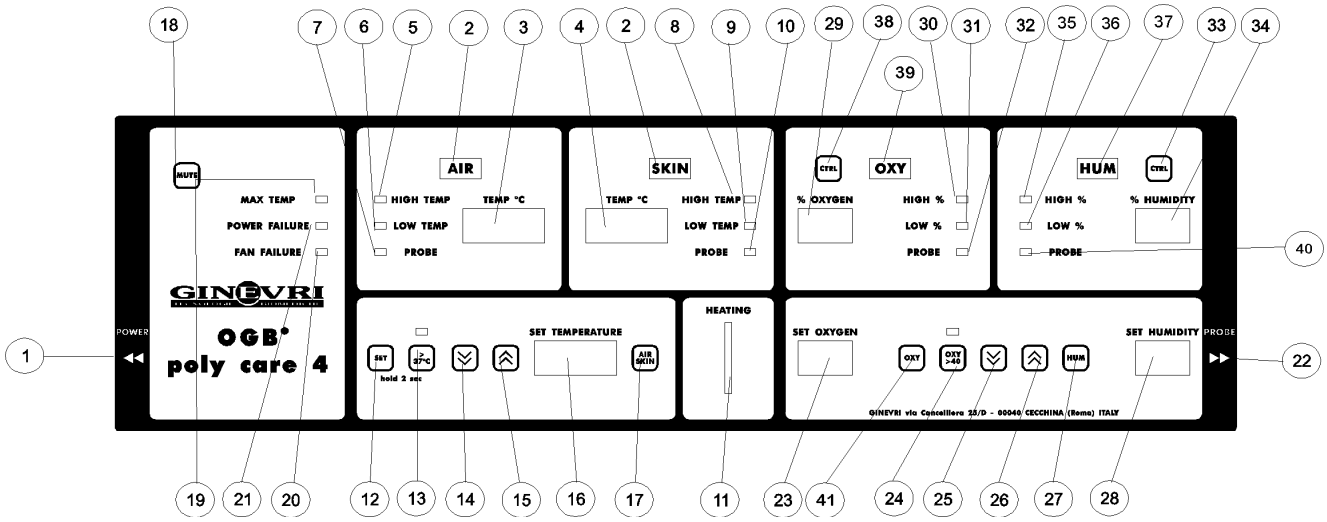
The ***OGB POLY CARE 4*** is a fully microprocessor driven Infant Incubator to provide both air and skin temperature control and constant monitoring of Oxygen Concentration and RH.
In addition, the heater output is proportional to the heat required by the little patients to maintain their own temperature and it is shown by the led bar scale changes. Heat outputs vary according to babies' needs and their dependence upon incubator, in order to create the best environmental conditions for the little patients, minimise temperature fluctuations and gradually wean the babies from the incubator system.

The ***OGB POLY CARE 4*** system provides:
a) accurate and automatic air temperature adjustment to achieve patient's set temperature;
b) temperature constant monitoring with settable high/low temperature alarms;
c) uniform temperature values inside the hood;
d) an indication of when it suitable to suspend the treatment, being the set patient temperature achieved without heat outputs (the led bar showing proportional heating is off);
e) Oxygen Concentration constant monitoring and servo-controlled adjustment with high/low O2 Concentration alarms;
f) RH constant monitoring and servo-controlled adjustment with high/low RH alarms.

OGB POLY CARE 4 Assembly mounted on closed cabinet trolley:
1. One piece injection moulded Polycarbonate transparent hood;
2. Port holes with sleeves and door releases;
3. Fire retarding mattress;
4. Polycarbonate patient tray equipped with *Smooth-Tilt* for the smooth adjustment of the posture bed in the Trendelmburg and Fowler positions;
5. Polycarbonate baffles;
6. Polycarbonate base complete with a humidity system and a air micro-filter;
7. Removable Control Panel (housed in the incubator base);
8. Air and /or O2 micro-filter (filtering capacity 0,5 micron)
9. Polycarbonate removable humidifier. It refills externally.
10. Humidifier cover lid equipped with device for the adjustment of RH inside the hood.



The ***OGB POLY CARE 4*** power requirements are 220V - 50/60 Hz.



3.2 **CONTROL PANEL**

1 **ON/OFF Green Switch** : the unit turns on/off when the switch is pressed/depressed. The power failure alarm operates if the switch is ON and the Power cord is unplugged or there is not Power Supply.

2 **AIR or SKIN Mode Led Indicator**, lights when Air or Skin is selected.

Actual Air Temperature in the hood in °C.

4 **Actual Skin Temperature** measured by the skin probe in °C.

5 **High Air Temperature Alarm**, it activates when the temperature inside the hood is 1°C higher than the set point. It blinks if muted.

6 **Low Air Temperature Alarm**, it activates when the temperature inside the hood is 3°C lower than the set point. It blinks if muted.

7 **Air Temperature Probe Failure Alarm**.

8 **High Skin Temperature Alarm**, it activates when the baby temperature is 1°C higher than set value. It blinks if muted.

9 **Low Skin Temperature Alarm**, it activates when the baby temperature is 1°C lower than the set value. It blinks if muted.

10 **Skin Temperature Probe failure Alarm**.

11 **Led Bar**, showing the heat output percentage.

12 **SET Key**, press and hold to set either Air and Skin temperature using the temperature arrows keys **(14)**

to lower and **(15)** to raise**.**

13 **>37 Key,** press and hold to set either Air or Skin temperatures above 37°C using the temperature arrow key **(14).**

14 **Temperature «DOWN» Arrow key** (it operates keeping Set Key **(12)** pressed).

15 **Temperature «UP» Arrow key** (it operates keeping Set Key **(12)** pressed).

16 **Set Temperature Display.** It shows either Set Air or Skin Temperature according to the selected mode.

17 **AIR-SKIN Key**, press to select either AIR or SKIN mode (it operates keeping Set Key **(12)** pressed).

18 **MUTE Key**, it mutes the audible alarms.

19 **MAX Temperature Alarm**, it activates at 38°C when the set temperature is $\leq$ 37°C or at 39°C when the set temperature is > 37°C. A separate Max Temperature Alarm will activate automatically at 40°C for any Set Temperature or over heating due to external sources (sun-ray, phototherapy lamps, radiators) and shut off the heating.
This alarm cannot be muted

20 **Fan Failure Alarm**, in case of fan malfunction it activates and the heating is shut off.
This alarm cannot be muted

21 **Power Supply Failure Alarm**.
This alarm cannot be muted

22 **Separate Sockets for Probe Assembly (right side) and O2 Sensor Probe (left side).**

23 **Set O2 Concentration Display**.

24 **OXY > 40 Key,** press and hold to set O2 concentration above 40% using the arrow key to set O2 concentration **(26).**

25 **O2/HUM Setting «DOWN» Arrow key** (it operates keeping Set OXY **(41)** or HUM keys **(27)** pressed).

26 **O2/HUM Setting «UP» Arrow key** (it operates keeping Set OXY **(41)** or HUM key **(27)** pressed).

27 **SET HUM Key**, press and hold to set Relative Humidity using the arrows keys **(25)** to lower and **(26)** to raise the percentage**.**

28 **Set Relative Humidity Display**.

29 **Actual O2 Concentration** in the hood in %.

30 **High O2 Concentration Alarm**, it activates when the O2 Concentration inside the hood is 10% higher

than the set point. It blinks if muted.

31 **Low O2 Concentration Alarm**, it activates when the O2 Concentration inside the hood is 10% lower than the set point. It blinks if muted.

32 **O2 Sensor Probe Failure Alarm**.

33 **CONTROL key**, press and hold to activate HUMIDITY Control Mode using HUM Key **(27)**.

34 **Actual RH Level** in the hood in %.

35 **High Humidity Alarm**, it activates when Humidity level inside the hood is 10% higher than the set point. It blinks if muted.

36 **Low Humidity Alarm**, it activates when Humidity level inside the hood is 10% lower than the set point. It blinks if muted.

37 **HUMIDITY Control Mode Led Indicator**, lights when HUM Mode is selected.

38 **CONTROL key**, press and hold to activate OXYGEN Control Mode using OXY Key **(41)**.

39 **OXYGEN Control Mode Led Indicator**, lights when OXY Mode is selected.

40 **RH Probe Failure Alarm**.

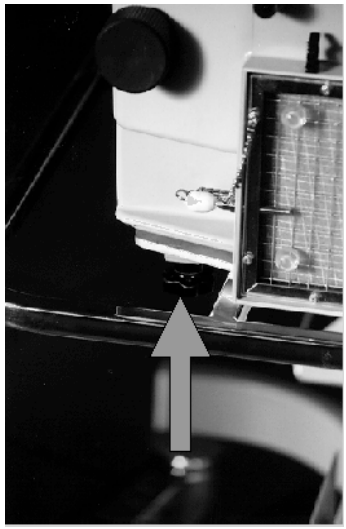
41 **SET O2 Key**, press and hold to set O2 Concentration using the arrows keys **(25)** to lower and **(26)** to raise**.**

3.3 UNPACKING

Typically, OGB Poly Care Line Incubators are shipped completely assembled in a wooden crate. Pay attention not to scratch or damage the surfaces removing the packaging materials.

3.4 INCUBATORS ASSEMBLY

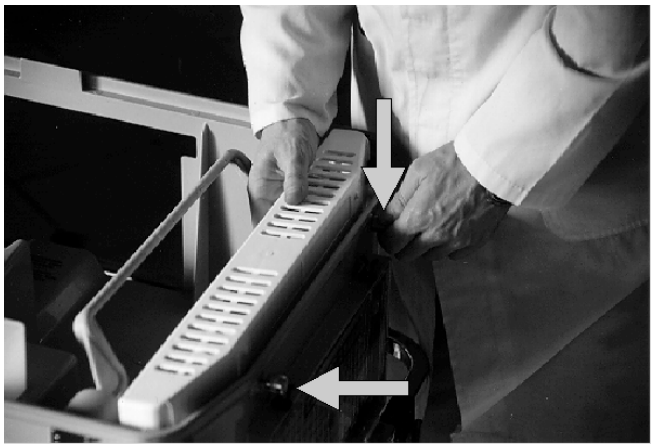
OGB Poly Care line Incubators are designed to allow an easy maintenance, disassembling and sterilisation.
Electrically powered elements are included in the control panel which can be easily with removed simply loosening four thumb screws.
All the components can be disassembled without using tools.



3.4.1 Base

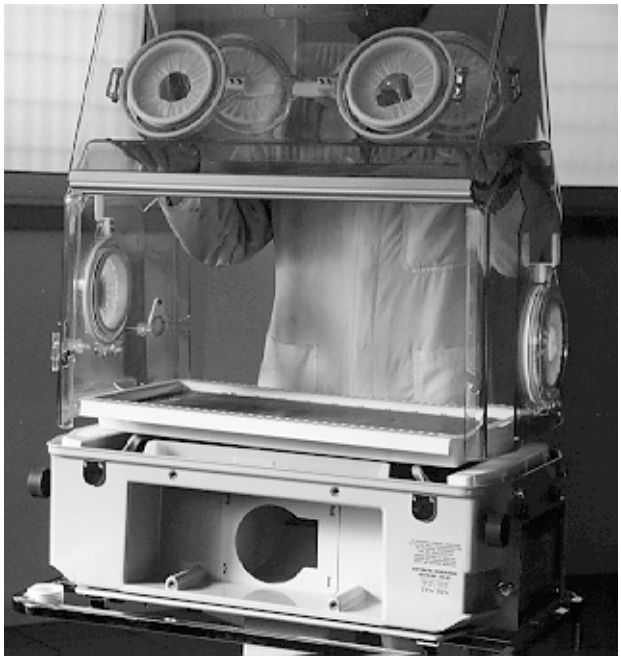
To avoid the Incubator tilting or falling, secure the Base to the cabinet as shown.
Place the Base on the stand and secure it using the clamping knobs on each edge.
Check to be certain Incubator is firmly secured to the stand . Do not place in service if not.

Install the Deflector on the base as shown .



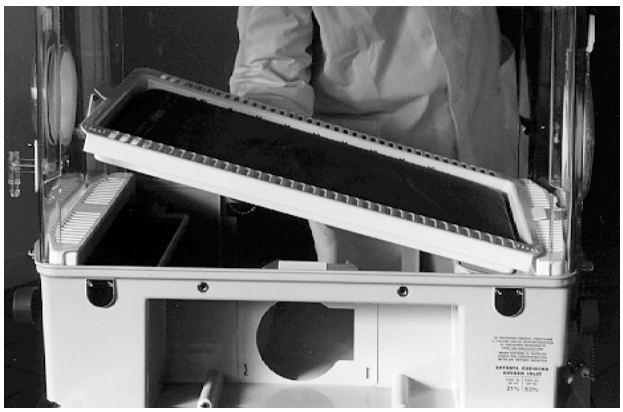
Secure both the Lexan baffles with the threaded pins supplied.

3.4.2 Hood



Lift the Hood as shown and place it on the base properly aligned on the threaded pins of the baffles. Secure the pins fast.

Lower both the elevators of the Tray Tilt Mechanism ***Smooth-Tilt*** turning the blue knobs on the left and right side of the base. Install the mattress tray as shown.



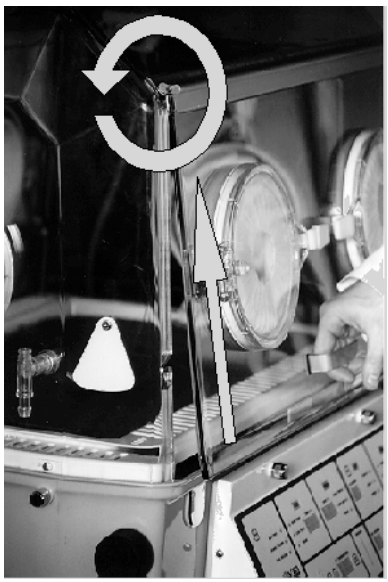
Both the doors are connected to the hood by means of a «slide out» type hinge in one piece with only two mounting screws for an absolute sterilisation as there are no hidden areas or critical points.

To disassemble the doors loose both the screws and slide the hinge out.

Both the doors should be kept close during routine operation. For infant safety, do not leave the infant unattended while the doors are open.

WARNING

Closing the doors, check that the bottom side of the door is inserted in the base slot as shown in the figure.



3.4.3 MICROFILTER

A **DIRTY** micro-filter may:

- Contaminate the air circulating in the hood;
- Obstruct the air intake, limiting air circulation;
- Affect oxygen concentration;
- Increase carbon dioxide concentration inside the incubator.

The micro-filter should be checked on routine basis and replaced whenever traces of dust become visible. In any case for every new patient.

Do not attempt to clean , wash or sterilise the micro-filter to use it again.

Instructions to replace the filter:

- remove air intake filter cover by pulling it out by means of the handle placed on the right side of the cover (as shown in the figure).
- Clean the micro-filter chamber and cover. Before installing the new filter, take note of the date replacing and write it down in the appropriate space on the right side of the filter. Install the new filter. The date must be always visible.

N.B. Ginevri s.r.l. cannot be responsible for the malfunctioning of the equipment and injury of the operator and/or patient which may be caused by the use of other types of filters.

3.4.4 Control Panel and Probes connectors

Install the Control Panel and secure it with the supplied thumb screws.

WARNING

The Controller heater can be sufficiently hot to cause burns; avoid moving or touching it until the unit has been switched off for at least 30 minutes.

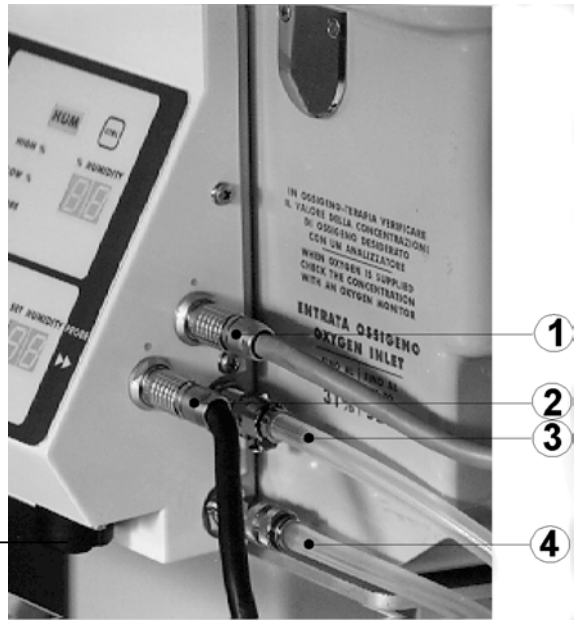
1 Probe Assembly connector and cable

2 O2 inlet from the gas supply (oxygen can be administered from a wall source or the oxygen cylinder)

3 O2 outlet and pipeline to the Head Box

4 Servo O2 outlet and pipline to Head Box (OGB Poly Care 4 only)

4a ***Hot Spot*** cable socket



- Connect Probe Assembly cable **(1)** to the ***OGB Poly Care 4.***
- Connect ***Servo-Steam*** cable **(2)** to the ***OGB Poly Care 4.***
- Connect Oxygen supplies **(3) (4)** to the ***OGB Poly Care 4*** using the pipelines supplied.
- Connect ***Hot Spot*** cable to the socket **(4a)** on the ***OGB Poly Care 4.***
- Connect Mains Electrical Supply cable **(7)** to the ***OGB Poly Care 4.*** Switching on the unit **(5)** check that the mains green indicator is lit on the switch.
- Connect O2 Probe cable **(6)** to the ***OGB Poly Care 4.***
- Insert O2 probe **(8)** into the support **(9)** supplied for calibration.

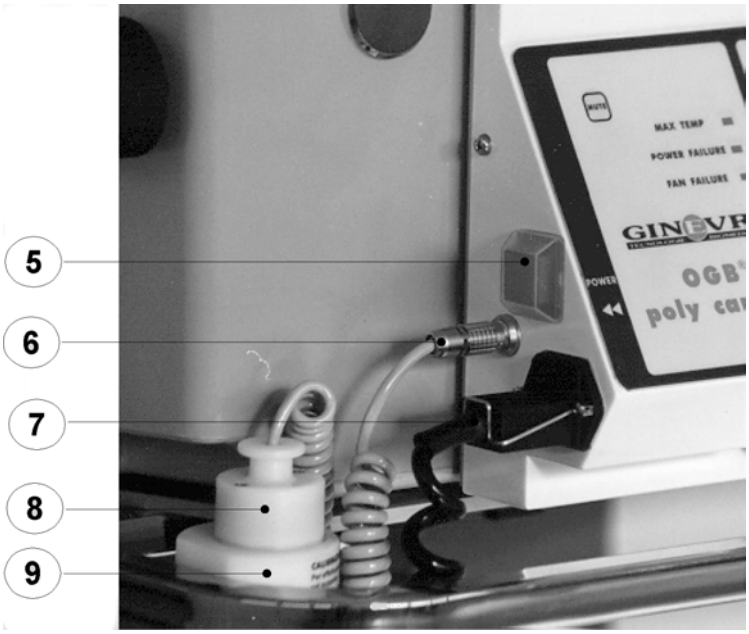
5 ON/OFF Green switch

6 O2 probe connector

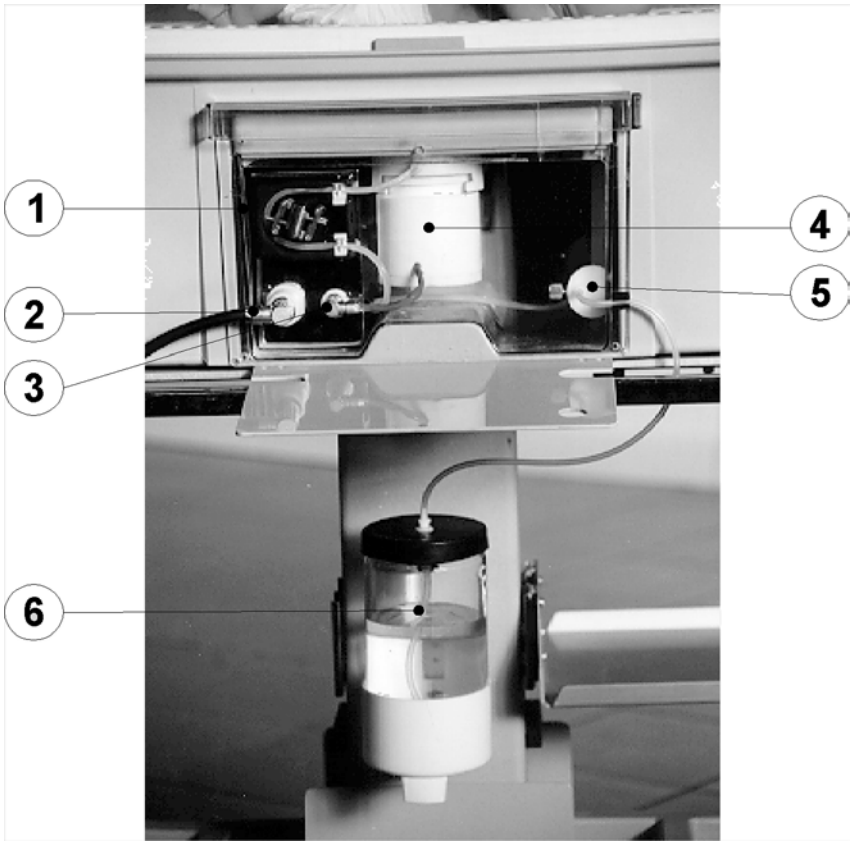
7 AC Power Cable

8 Oxygen Probe

9 Oxygen probe support for calibration



3.4.5 Servo-Steam Humidifier



OGB ***Poly Care 4*** is provided with ***Servo-Steam*** humidifier that servo-controls set humidity level inside the hood up to a value of 100%.
The system consists of:

1 Peristaltic pump

2 Probe Cable connecting the system to the control panel

3 Evaporator Connector

4 Evaporator

5 Water pipeline connector

6 Water reservoir

Insert ***Servo-Steam*** humidifier into the Humidity Chamber housed in the Incubator Base rear side and connect the Probe cable (2) to the control panel. Humidifier socket is placed on the right side of the control panel and it is labelled ***Servo-Steam Probe***.
Insert the water reservoir (6) into the support on the trolley and fill it with sterile distilled water. Connect the water pipeline to the inlet on the evaporator lid making it pass through the connector (5) and the pump clamps.

The system can be withdrawn from the base simply pressing the latches on the left and right side of the same. This allows the cleaning and sterilisation of the system avoiding condensation and spores depositing.
It is possible to remove the system keeping the patient inside the incubator without using any special tools.

WARNING
Condensation may form on the inside of the hood at the higher humidity values settings. The amount of condensation will depend on the difference between room temperature and incubator temperature.

3.4.6 Radiant Heater Hot Spot

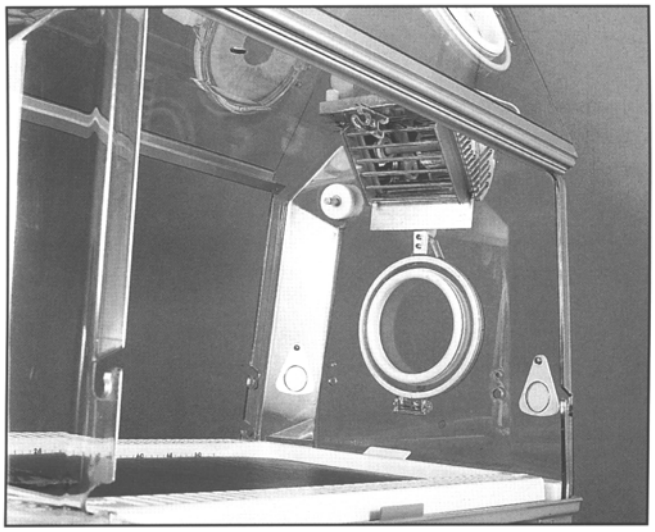
OGB ***Poly Care 4*** can be equipped with new ***Hot Spot*** system (optional).
The ***Hot Spot*** is an infrared radiant heater controlled by the incubator SKIN Mode operation system which allows to maintain constant pre-set baby skin-temperature even with both incubator doors open.

The system consists of:

1 Hood port cover lid

2 Radiant heater

3 ***Hot Spot*** module



- Remove the port cover lid from the hood right side.
- Insert the Radiant Heater through the port on the hood right side and secure it using the two thumb-screws supplied for the port cover lid.

WARNING
Check that both thumb screws are fully tightened before proceeding.

- Insert the ***Hot Spot*** module into the slot on the right side of the trolley.
- Secure the cable connecting the radiant heater and the module with the clamps provided.
- Loosen the screw-cap of the Hot Spot cable socket on the right side of the control panel. This socket is labelled: ***Hot Spot***
- Screw ***Hot Spot*** module cable to the socket.
- Press the switch on the Hot Spot Module to power the system on.

Hot Spot will now automatically adjust radiant heater output to correct the difference between the actual patient temperature and the required level set by the user.

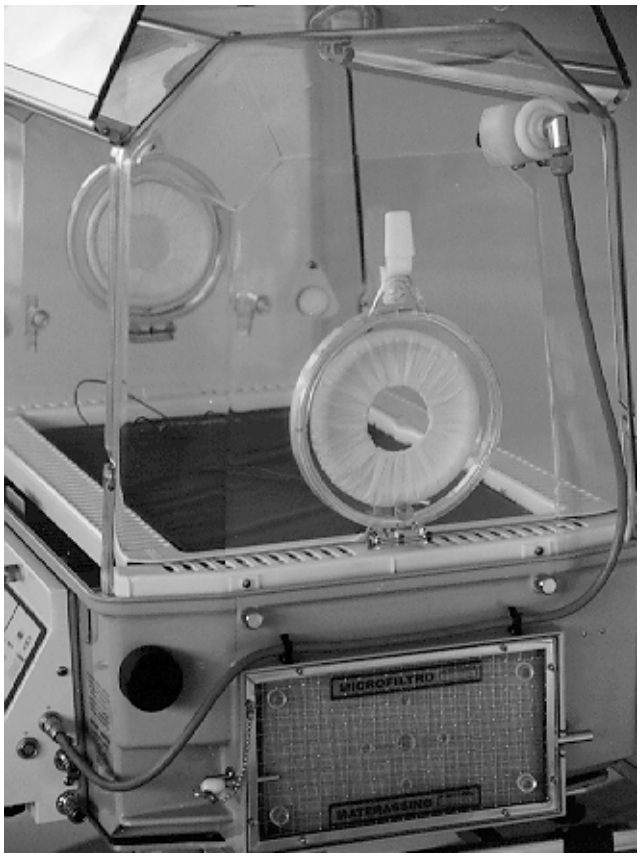
CAUTION
Hot Spot activates only when OGB ***Poly Care 4*** is operating in SKIN Mode Control. A pulsating audible alarm indicates that the system is on. This alarm is self-resetting and reactivates automatically after a 10 minute delay.

WARNING
HOT SPOT SHOULD BE USED WITH A LEAST ONE DOOR OPEN. IF BOTH DOORS ARE CLOSED DO NOT ADMINISTER OXIGEN.

4. OPERATION

4.1 OPERATING INSTRUCTIONS

1. Connect the power cord to 220V-50Hz.
2. Press ON the Power
3. Connect the Probe Assembly to the Probe Assembly socket **(22).**
4. Insert the Probe Assembly end through the hole on the top of the hood as shown in the Figures.



5. Air Temperature value will be displayed on **(3).**

6. RH value will be displayed on **(34)**

7. Connect the plug of the Skin Probe to the Skin Probe socket placed on the bottom side of the Probe Assembly**.**

8. When the infant is on its back or side, put the tip of the probe to the midline of the abdomen, halfway between the umbilicus and the xyphoid**.** When the infant is prone, the probe should be on the infant's back. The skin area where the probe is to be placed should be thoroughly cleaned and dried before the probe is placed on the skin. The Skin Probe must be attached in complete contact with the skin. Ginevri heart shaped ***Reflectors*** (p/n 565) are designed for this purpose.

WARNING
The probe must never be placed under the infant or used rectally.

9. Skin Temperature value will be displayed on **(4).**

10. Check the water level of the humidifier reservoir, and if necessary fill it to the gauge line with sterile distilled water.

11. Connect the power cord to 220V-50Hz.

12. Press ON the Power supply Switch **(1).** The display panel will show the memorised values.

13. Warmup the incubator until the temperature inside the hood is stabilised at the set value. Putting the equipment first into use or using it immediately following a period of storage, allow approximately 30 minutes for pre-heating to be performed.

14. If the temperature external is higher than that required by the patient, put some ice inside the humidifier reservoir. In this way, the temperature decreases and the operator may set the right value.

15. The ***OGB Poly Care 4*** is provided with an Assembly of 5 probes that guarantee the utmost reliability. Two probes monitor the Air temperature. The second Air probe becomes operative whenever the first probe fails. In this case the probe alarm **(7)** is flashing. Should be both the probes faulty, the probe visual alarm light is steady. The third probe (Skin probe) monitors the Skin temperature, in case of failure, the probe audio-visual alarm **(10)** activates and the incubator will start to operate automatically in Air Mode at 33 °C. The fourth probe is connected to the Max Air Temperature alarm with separate safety circuit. The fifth probe (Humidity probe) monitors the RH inside the hood. In case of failure of this probe the Humidity Probe failure alarm **(40)** activates.

4.1.1 O2 Calibration Procedure

Connect the plug of the Oxygen Sensor Probe to the O2 Sensor Probe socket **(22)**, as shown in the figure.

Flashing red LED letters "**CA**" will be displayed on **(29)** to indicate that calibration should be performed before proceeding.

4

Insert the O2 Sensor Probe in the support supplied for calibration as shown in the figure.
Check that the Sensor pin is inserted in the support slot.
Displayed "**CA**" letters become steady to indicate that automatic calibration is activated.

WARNING
If "**CA**" indicator goes on flashing, the sensor is not being calibrated.
In this case:

1. Repeat calibration procedure and check that the sensor probe pin is correctly inserted into the support slot.
2. The sensor is at the end of its useful life and must be replaced.

Allow approximately 30 seconds for a O2 concentration of **21%** to be displayed.

WARNING
Should the sensor be exhausted, calibration will not be performed and the alarm PROBE will be activated.

During the calibration, the O2 concentration of the environment should be of 21% to avoid faulty readings or probe failure alarms.

Before proceeding it is advisable to check the accuracy of the readings measuring gasses with known O2 concentrations: Air (21%) and pure Oxygen (100%). If the display cannot be adjusted to reach 99% (measuring pure Oxygen) or does not return to 21% (+/- 1%) then the sensor must be replaced.

To achieve accurate FiO_2 readings the Sensor Probe should have the same temperature of hood. It is advisable to place it inside the hood during pre-heating operations.

GINEVRI recommends that calibration procedure is performed according to the following schedule:

- Before the equipment is first put into use.
- Before the equipment is used immediately following a period of storage.
- Once every 24 hours when the equipment is in constant use.
- Whenever primary power to the incubator is interrupted for any reason.

Hang the O2 Sensor Probe by means of the hood supports or insert it into the Head Box support as showed in the figure.

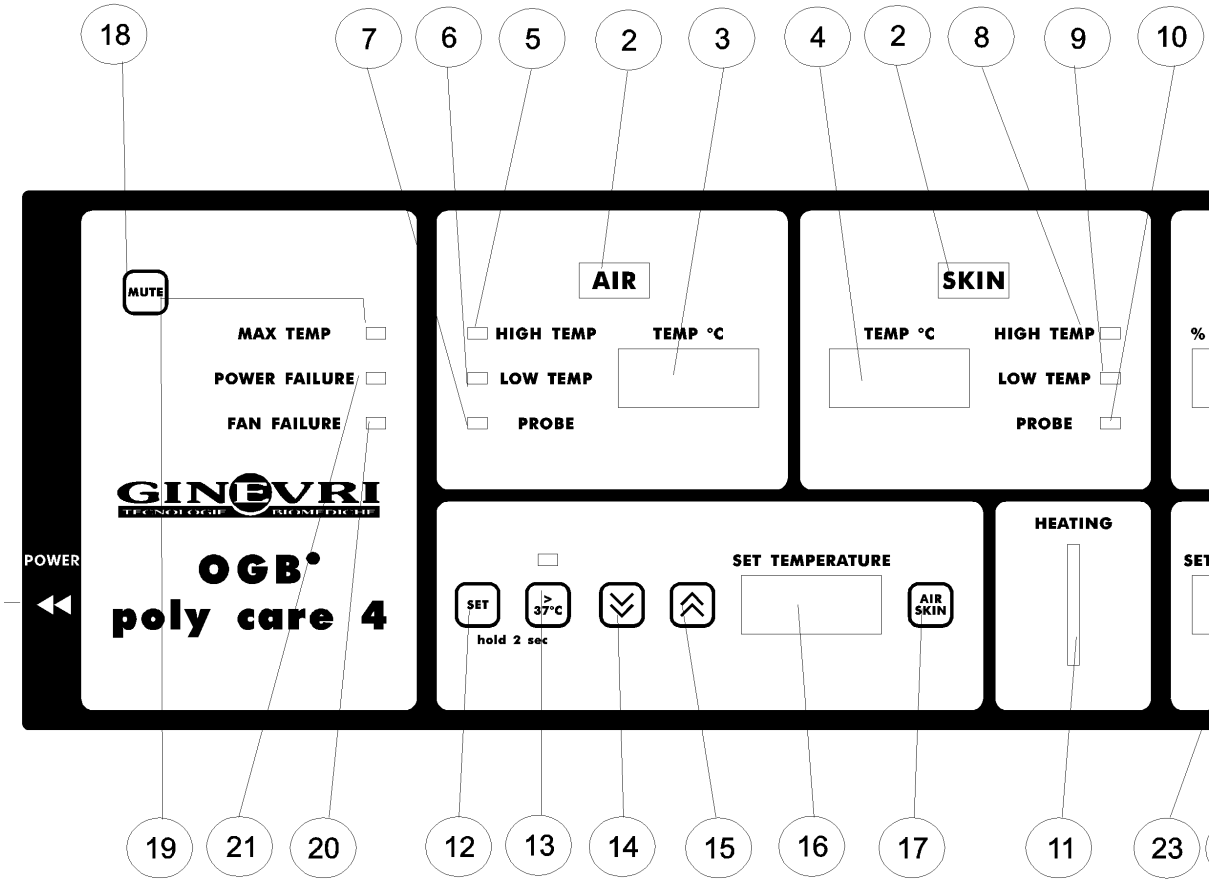
WARNING

Care should be taken in placing the O2 sensor probe apeak, either in the hood or in the head box, in order to prevent the accuracy of the readings from being affected.

4.2 OPERATION MODES

The microprocessor system controls both Air (AIR Mode) and Skin (SKIN Mode) temperature with proportional heating. The heating percentage is displayed on a 5 segment LED Bar.

4.2.1 Air Temperature Control



2 **AIR or SKIN Mode Led Indicator**, lights when Air or Skin is selected.

3 **Actual Air Temperature** in the hood in °C.

5 **High Air Temperature Alarm**, it activates when the temperature inside the hood is 1°C higher than the set point. It blinks if muted.

6 **Low Air Temperature Alarm**, it activates when the temperature inside the hood is 3°C lower than the set point. It blinks if muted.

7 **Air Temperature Probe Failure Alarm**.

11 **Led Bar**, showing the heat output percentage.

12 **SET Key**, press and hold to set either Air and Skin temperature using the temperature arrows keys **(14)**

to lower and **(15)** to raise**.**

13 **>37 Key,** press and hold to set either Air or Skin temperatures above 37°C using the temperature arrow key **(14).**

14 **Temperature «DOWN» Arrow key** (it operates keeping Set Key **(12)** pressed).

15 **Temperature «UP» Arrow key** (it operates keeping Set Key **(12)** pressed).

16 **Set Temperature Display.** It shows either Set Air or Skin Temperature according to the selected mode.

17 **AIR-SKIN Key**, press to select either AIR or SKIN mode (it operates keeping Set Key **(12)** pressed).

18 **MUTE Key**, it mutes the audible alarms.

19 **MAX Temperature Alarm**, it activates at 38°C when the set temperature is ≤ 37°C or at 39°C when the set temperature is > 37°C. A separate Max Temperature Alarm will activate automatically at 40°C for any Set Temperature or over heating due to external sources (sun-ray, phototherapy lamps, radiators) and shut off the heating.
This alarm cannot be muted

The Air temperature control activates automatically at 33°C when the incubator starts to work. The microprocessor system controls air temperature with proportional heating. The heating percentage is displayed on a 5 segments LED Bar **(11).**
To change Air Temperature from 20°C to 37°C press SET key **(12)** and **(14)** or **(15)** keys at the same time to decrease or increase set temperature (0,1°C step).
To increase temperature over 37°C press **(12)** key and **(13)** key at the same time.

WARNING
Temperature Override Mode > 37 °C key is inactive until the Set Temp has been set to 37°C.

Pre-set temperature values are memorised and they will be stored in case of power failure or black out.

Actual air temperature is displayed by the Air temperature display **(3).**

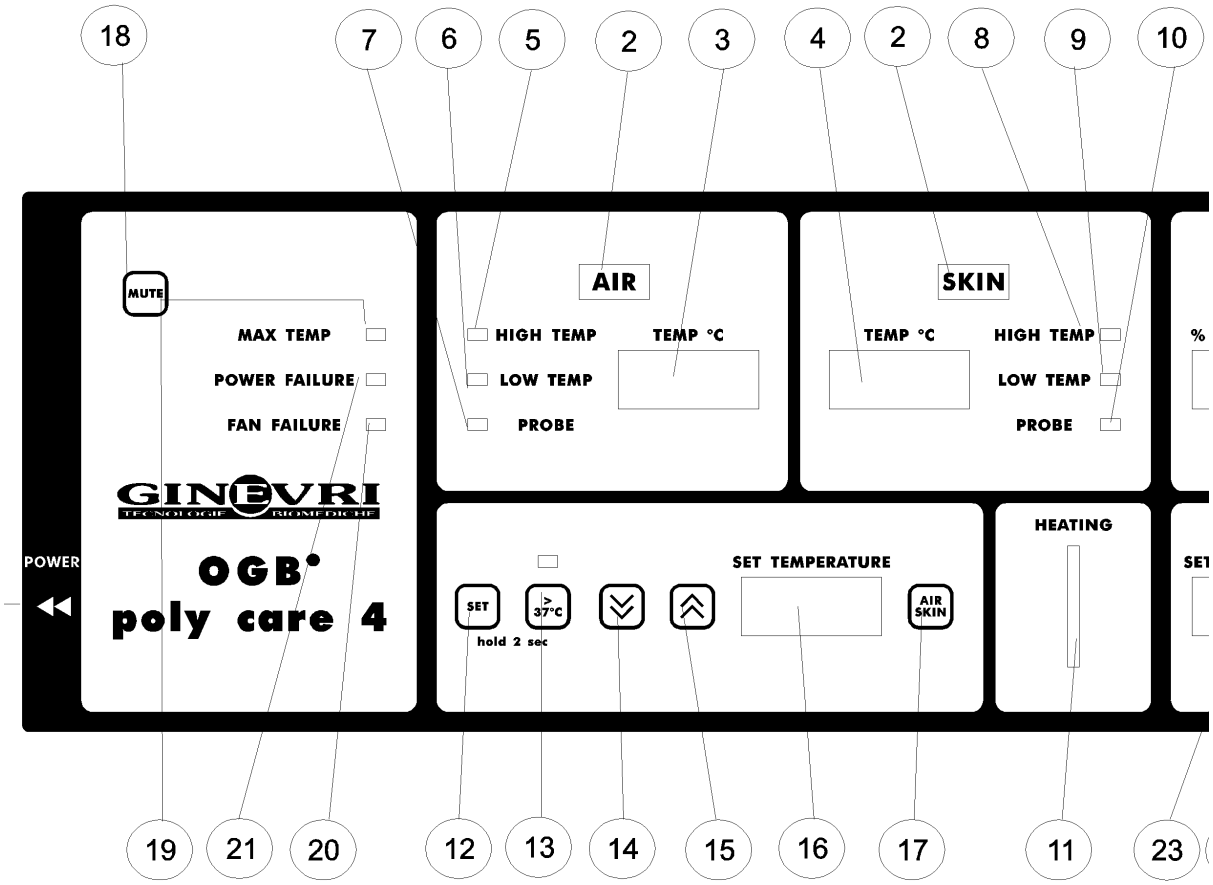
High/Low Air Temperature Alarms

The high and low temperature alarms **(5) - (6)** are automatically pre-set setting a new temperature. The alarm activates when actual air temperature is 1°C higher than set temperature or 3°C lower than the set temperature.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will be reactivated.
AIR Temp. Probe Failure Alarm (7) is an immediate visual and audible alarm which cannot be muted.

Max Air Temperature Alarm

If the set temperature is lower or up to 37°C, an audio-visual Max Temperature alarm **(19)** activates when the temperature exceeds 38°C. If the set temperature is between 37°C or 38°C an audio-visual alarm activates **(19)** when the temperature exceeds 39°C. This alarm cannot be muted until the Max Temp. alarm condition is corrected.

4.2.2 Skin Temperature Control



2 **AIR or SKIN Mode Led Indicator**, lights when Air or Skin is selected.

4 **Actual Skin Temperature** measured by the skin probe in °C.

8 **High Skin Temperature Alarm**, it activates when the baby temperature is 1°C higher than set value. It blinks if muted.

9 **Low Skin Temperature Alarm**, it activates when the baby temperature is 1°C lower than the set value. It blinks if muted.

10 **Skin Temperature Probe failure Alarm**.

11 **Led Bar**, showing the heat output percentage.

12 **SET Key**, press and hold to set either Air and Skin temperature using the temperature arrows keys **(14)** to lower and **(15)** to raise**.**

13 **>37 Key,** press and hold to set either Air or Skin temperatures above 37°C using the temperature arrow key **(14).**

14 **Temperature «DOWN» Arrow key** (it operates keeping Set Key **(12)** pressed).

15 **Temperature «UP» Arrow key** (it operates keeping Set Key **(12)** pressed).

16 **Set Temperature Display.** It shows either Set Air or Skin Temperature according to the selected mode.

17 **AIR-SKIN Key**, press to select either AIR or SKIN mode (it operates keeping Set Key **(12)** pressed).

18 **MUTE Key**, it mutes the audible alarms.

Skin temperature activates automatically at 36 °C when the incubator starts to work. The relative amount of heat being provided to achieve set Skin temperature is displayed on a 5 segments LED Bar **(11).**
Press Set key **(12)** and AIR/SKIN **(17)** key to set SKIN Operation Modes.
To change Skin Temperature from 25°C to 37°C press SET key **(12)** and **(14)** or **(15)** keys to decrease or increase temperature (0,1°C step).
To increase temperature over 37°C press **(13)** and **(15)** key at the same time.

WARNING
Temperature Override Mode > 37 °C key is inactive until the Set Temp has been set to 37 °C.

The pre-set temperature values are memorised and they will be stored in case of power failure or black out.

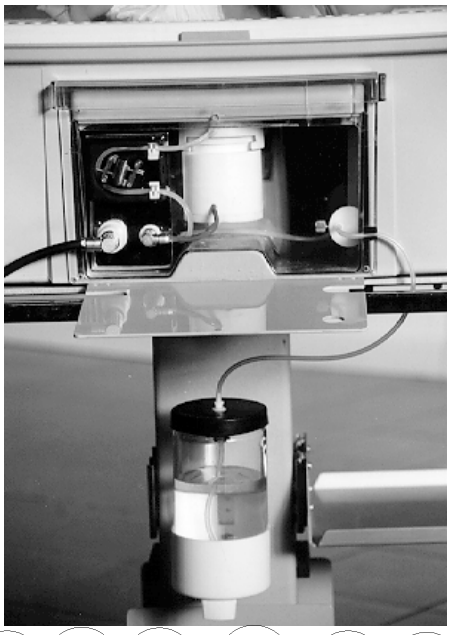
A temperature sensing probe is attached directly to the infant's skin; the information from the probe is supplied to the heater control circuitry which proportions the heater output to maintain the Baby's Temperature at the set Skin Temperature.

Actual baby temperature is displayed by the Skin temperature display **(4).**

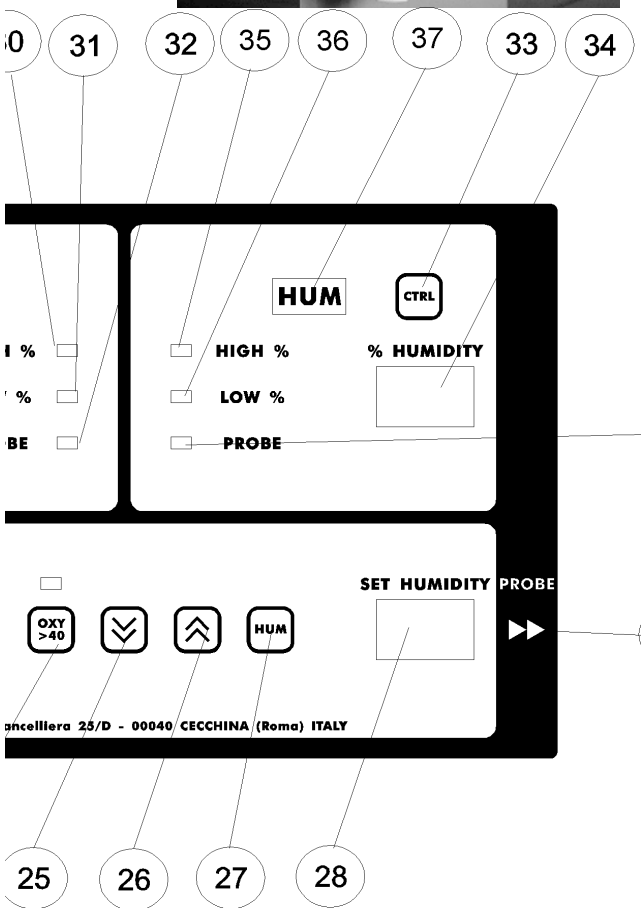
High/Low Skin Temperature Alarm

The high and low temperature alarms **(8)** - **(9)** are automatically pre-set when setting a new temperature. The alarm activates when skin temperature is either 1°C higher or lower than the set skin temperature.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will be reactivated.
SKIN Temp. Probe Failure Alarm (10) is an immediate visual and audible alarm which cannot be muted.

4.2.3 Relative Humidity Servo-Controlled System



Poly Care 4 is provided with a micro-processor driven humidifier: ***Servo-Steam.***
Servo-Steam humidifier servo-controls set humidity level inside the hood up to a value of 99%.
It generates sterile humidity using even simple tap water.
The humidity generating system guarantees absolute sterility because the evaporator, located in the standard humidifier housing, is isolated from the patient environment, works at 135 °C, the water reservoir is located outside the incubator and, therefore, in the patient chamber enters and diffuses only vapour.



25 **HUM Setting «DOWN» Arrow key** (it operates keeping Set HUM keys **(27)** pressed).

26 **HUM Setting «UP» Arrow key** (it operates keeping Set HUM key **(27)** pressed).

27 **SET HUM Key**, press and hold to set Relative Humidity using the arrows keys **(25)** to lower and **(26)** to raise the percentage**.**

28 **Set Relative Humidity Display**.

33 **CONTROL key**, press and hold to activate HUMIDITY Control Mode using HUM Key **(27)**.

34 **Actual RH Level** in the hood in %.

35 **High Humidity Alarm**, it activates when Humidity level inside the hood is 10% higher than the set point. It blinks if muted.

36 **Low Humidity Alarm**, it activates when Humidity level inside the hood is 10% lower than the set point. It blinks if muted.

37 **HUMIDITY Control Mode Led Indicator**, lights when HUM Mode is selected.

Check to be certain that ***Servo-Steam*** system is properly installed following the assembling instruction as described previously.
Fill in the water reservoir.

WARNING
It is advisable to use distilled water to prevent calcium in the evaporator.

Turning the incubator on, actual Relative Humidity in the hood will be monitored and displayed on **(34)** (2 red led digits).
Depress and hold **CTRL (33)** to activate HUMIDITY Control Mode using HUM Key **(27)**. The most recent setting will then be redisplayed on **(28)** (2 green led digits). To change set values from 0% to 99% depress and hold HUM Key **(27)** and adjust Set Relative Humidity display to the required level by simultaneous depression of either the **(25)** key to increase or **(26)** key to decrease (1% step).
Poly Care 4 Humidity Controller will now automatically adjust delivered vapour to correct the difference between the RH level within the hood and the required level set by the user.
If primary power to the incubator is interrupted for any reason the most recent RH setting will remain in memory.
Condensation may form inside the hood at the higher humidity values settings. The amount of condensation will depend on the difference between room temperature and incubator temperature.

High/Low RH Alarm

The high and low RH alarms **(35) - (36)** are automatically pre-set when setting a new RH level. The alarm activates when actual RH is either 10% higher or lower than the set value.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will be reactivated.
RH Probe Failure Alarm (40) is an immediate visual and audible alarm which cannot be muted.

4.2.4 Oxygen Concentration Servo-Controlled System

OGB ***Poly Care 4*** is provided with a sophisticated electronic system which will enable optimum monitoring and control of O2 concentration in the incubator hood or in the head-box in the range 21-99% with low flow rates.
The system improves patient therapy ensuring that the Oxygen concentration level set by the clinician is maintained to a very tight tolerances.

WARNING
For safety reasons it is not possible to set oxygen concentrations above 52% in the hood. Higher concentrations up to 99% can be easily achieved in the head box.

23 **Set O2 Concentration Display**.

24 **OXY > 40 Key,** press and hold to set O2 concentration above 40% using the arrow key to set O2 concentration **(26).**

25 **O2 Setting «DOWN» Arrow key** (it operates keeping Set OXY **(41)** pressed).

26 **O2 Setting «UP» Arrow key** (it operates keeping Set OXY **(41)** pressed).

29 **Actual O2 Concentration** in the hood in %.

30 **High O2 Concentration Alarm**, it activates when the O2 Concentration inside the hood is 10% higher than the set point. It blinks if muted.

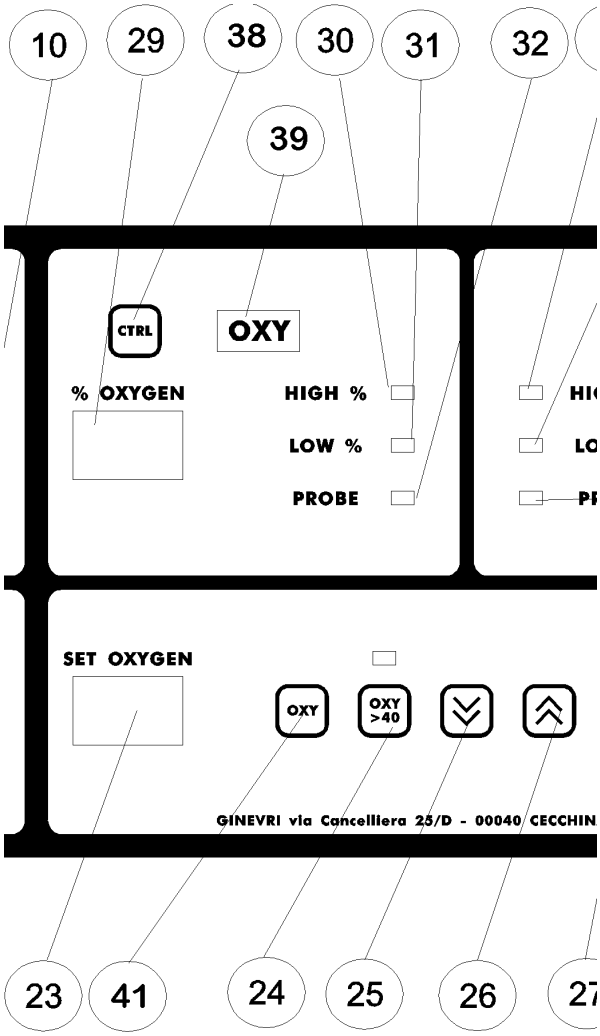
31 **Low O2 Concentration Alarm**, it activates when the O2 Concentration inside the hood is 10% lower than the set point. It blinks if muted.

32 **O2 Sensor Probe Failure Alarm**.

38 **CONTROL key**, press and hold to activate OXYGEN Control Mode using OXY Key **(41)**.

39 **OXYGEN Control Mode Led Indicator**, lights when OXY Mode is selected.

41 **SET O2 Key**, press and hold to set O2 Concentration using the arrows keys **(25)** to lower and **(26)** to raise**.**



Check to be certain that the oxygen supply and the O2 sensor cable are properly connected following the assembling instruction as described previously.

Perform the calibration procedure as described previously.
Once calibration procedure has been performed, actual O2 Concentration in the hood will be monitored and displayed on **(29)** (2 red led digits).
Depress and hold **CTRL (38)** to activate OXYGEN Control Mode using OXY Key **(41)**. The most recent setting will then be redispalyed on **(23)** (2 green led digits). To change set values from 21% to 40% depress and hold OXY Key **(41)** and adjust Set Oxygen concentration display to the required level by simultaneous depression of either the **(26)** key to increase or **(25)** key to decrease (1% step).

To change set values from 41% to 99% depress and hold OXY>40 Key **(24)** and adjust Set Oxygen concentration display to the required level by simultaneous depression of either the **(26)** key to increase or **(25)** key to decrease (1% step).

WARNING
Oxygen Override Mode > 40 % key is inactive until the O2 concentration has been set to 40%.
For safety reasons it is not possible to set oxygen concentrations above 45% in the hood. Higher concentrations up to 99% can be easily achieved in the head box.

Poly Care 4 Controller will now automatically adjust delivered gas to correct the difference between the oxygen concentration, either within the hood or the head box, and the required level set by the user.

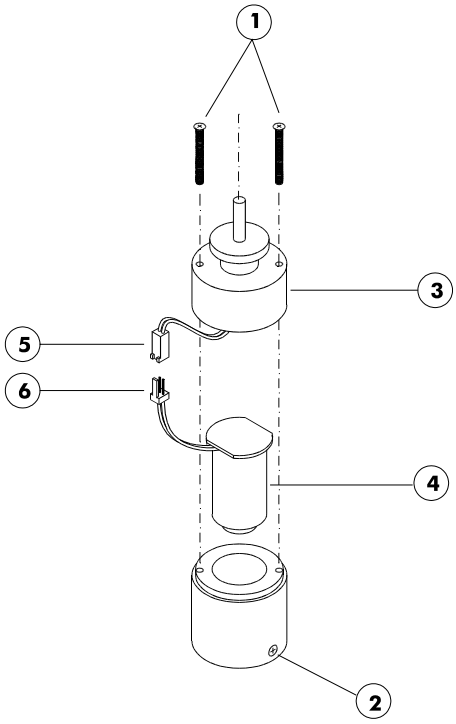
WARNING
If primary power to the incubator is interrupted for any reason the most recent O2 setting will remain in memory. Calibration procedure must be performed in these cases.

High/Low O2 Alarm

The high and low O2 alarms **(30)** - **(31)** are automatically pre-set when setting a new O2 concentration. The alarm activates when actual O2 concentration is either 10% higher or lower than the set value.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will be reactivated.
O2 Probe Failure Alarm (32) is an immediate visual and audible alarm which cannot be muted.

O2 Sensor replacement

The O2 sensor **(4)** is a unique galvanic cell. Although attractive product benefits include longer life and long shelf life, galvanic sensors appear to lose efficiency in case of prolonged shelf life, it is then advisable not to keep in storage a number of pieces far exceeding those necessary.
The life time of GINEVRI O2 sensor can be specified by %-hours [Oxygen concentration (%) x Time (hours)]: 900,000 – hours.
This fact mean that the expected life time in ambient conditions (21% O2 at 20 °C) is 5 years.
To replace the sensor (**P/N 10267A30**) loosen both the screws on the probe cap **(1)** and the screw that secure the sensor probe **(2)**, disconnect both the connectors **(5) (6)**, remove the sensor and replace it with a new one.



4.3 ALARM DEVICES

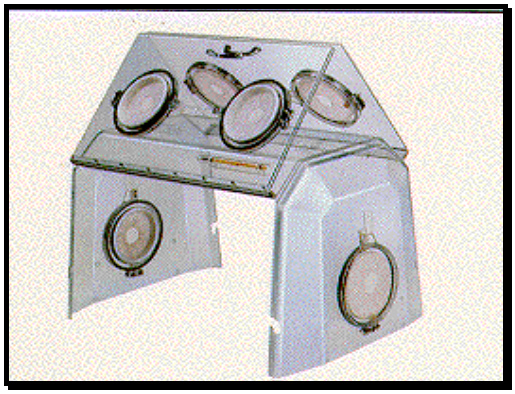
4.3.1 Power Failure Alarm

The power failure audio-visual alarm **(21)** will sound when the power supply is interrupted.
Check the power failure alarm for proper operation before using the incubator. Remove the power cord from the wall outlet, the buzzer should sound.
This alarm cannot be muted until the alarm condition is corrected. In this case is necessary to reset the system setting the incubator Power switch to off before proceeding.

4.3.2 Fan Block Alarm

If the fan assembly is faulty the audio-visual alarm **(20)** activates indicating the fan-block.
This alarm cannot be muted until the alarm condition is corrected. In this case is necessary to reset the system setting the incubator Power switch to off before proceeding.

4.4 HOOD ASSEMBLY



The hood is made of one-piece injection moulded polycarbonate. Lexan (Polycarbonate) is more performing than traditional Acrylic Plexiglas and it has the following features:

- UNBREAKABLE;
- MOULDED IN A SINGLE PIECE WITHOUT JUNCTIONS, for an easy and absolute sterilisation;
- ATHERMIC: it does not disperse heat and guarantees against contact burns;
- SILENT: it guarantees minimum noise inside the incubator (less than 45 dB);
- FIRE RETARDING;
- HIGH TEMPERATURE RESISTANT (150°C);
- CHEMICALS PROOF;
- NON-TOXIC.

OGB Poly Care 4 Incubator outperform in every aspect the traditional incubator Acrylic/Plexiglas hoods. This means also:

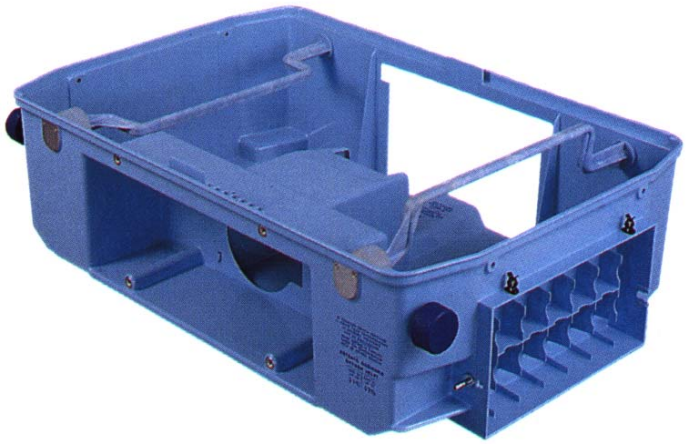
- Improved internal visibility;
- Easy cleaning and sterilisation;
- No image distortion;
- Unequalled Width.

The incubator hood is provided with 2 doors, 6 portholes and tubing access ports. The two doors can be opened upwards at the same time to allow easy and immediate care team access from both side.

WARNING

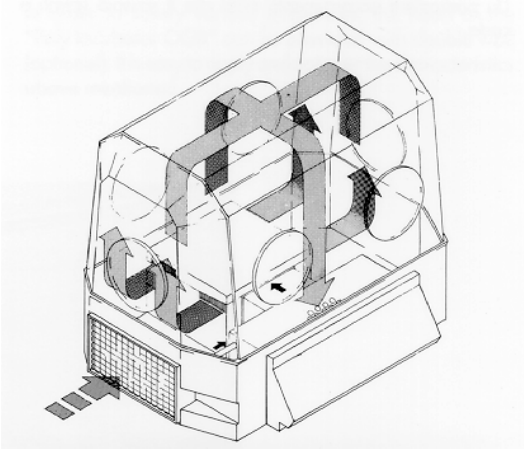
Closing the doors, check that the bottom side of the door is inserted in the base slot.
The six portholes with sleeves allow access to patient without altering the microclimate.
The "slide out" type hinges allow easy cleaning and absolute sterilisation.

4.5 BASE



The base is made of polycarbonate injection moulded in one-piece, with smooth edges.
The assembly allows easy cleaning and maintenance.
The base consists of patient bed tray, micro-filter assembly, humidity reservoir, oxygen inlets.

4.6 AIR CIRCULATING SYSTEM



The forced air circulating system (36 liters per minutes)[1] provides a constant interchange of air. The external air, oxygen enriched, if necessary, enters the incubator through a high efficiency micro-filter, is directed by a fan through the heating chamber, being driven over humidification chamber with manual external adjustment flows through the patient tray vents and enters the hood without generating harmful turbulence around the newborn.
The slight "Venturi effect" which is created along the four sides of the hood towards the centre, guarantees the quiet and uniform distribution of microclimate around the patient and the elimination of the CO2.

WARNING

Proper temperature control depends on continuos, unobstructed air circulation.

Do not cover air circulation vents around the bed as obstruction will result in less efficient air circulation and increased CO2 level.

4.7 OXYGEN INLETS

The ***OGB Poly Care 4*** is provided with two inlets for controlled administration of pure oxygen, respectively **31%** and **52%**, and both inlets are located on the air-filtering assembly.

WARINING

Oxygen concentration higher than 52% could be dangerous for infants. They can increase the risk of retinopathy. Therefore, arterial blood gas monitoring is extremely important when oxygen enriched environment is necessary.

OXYGEN CONCENTRATION SHOULD BE CHECKED WITH AN OXYGEN ANALYSER AND A PULSE OXYMETER.

4.7.1 Oxygen Concentration Guide (31%)

With the flowmeter and the oxygen hose connected to the 31% inlet

Rate of Flow	**Oxygen Concentration**
l.p.m. 1	22,7 %
l.p.m. 2	23,7 %
l.p.m. 3	25,1 %
l.p.m. 5	29 %
l.p.m. 6	29,7 %
l.p.m. 7	30,3 %
l.p.m. 8	31 %
l.p.m. 9	31,5 %
l.p.m. 10	31,5 %

[1] Considering that:

- The maximum production of CO2 by newborn placed in an incubator is 36ml/min.
- In relation to the ambient air, the concentration of CO2 in the incubator cannot go above one per thousand 1‰
- It is evindent that an incubator must gurantee a fresh-air flow of 36 lt./min. (36 ml/min=0.036 lt/min)

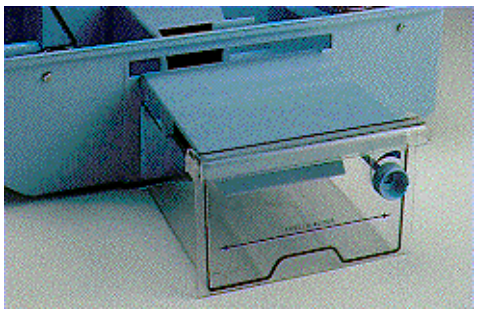
4.7.2 Oxygen Concentration Guide (52%)

With the flowmeter and the oxygen hose connected to the 52% inlet.

Rate of Flow	**Oxygen Concentration**
l.p.m 5	31 %
l.p.m. 10	43,5 %
l.p.m. 15	43,5 %
l.p.m. 18	46 %
l.p.m. 20	51,5 %
l.p.m. 25	52 %
l.p.m. 30	52 %

4.8 STANDARD HUMIDITY SYSTEM *(*Optional for OGB Poly Care 4 Incubators)

The standard humidity system consists of a transparent polycarbonate tank, housed in Incubator Base rear side, allowing water level constant monitoring.
This system allows to adjust the RH level up to 90% turning clockwise the blue knob.
The water tank can be withdrawn from the base simply pressing the latches on the left and right side of the same. This allows the cleaning and sterilisation of the reservoir avoiding condensation and spores depositing.



It is possible to remove the reservoir when the patient is inside the incubator.
Fill the reservoir to the gauge line with sterile distilled water. When removing the reservoir, it is possible to remove also the humidity control system without using any special tools.
Since tubing, screws have been avoided, the humidifier can be easily disassembled for an absolute cleaning.
Condensation may form inside the hood at the higher humidity values settings. The amount of condensation will depend on the difference between room temperature and incubator temperature.
The humidity level should range from 50% to 65%. Microclimate hoods are suggested when a humidified, high temperature, oxygenated environment is considered necessary.
We list below a table of ranges depending on three different knob positions : MINIMUM - MEDIUM - MAXIMUM.

AMBIENT TEMPERATURE	**ROOM HUMIDITY**	**INCUBATOR TEMP.**	**INCUBATOR HUMIDITY Minimum - Medium - Maximum**		
24°C	52%	32°C	60/65	65/75	75/90
		35°C	53/63	63/73	73/83

4.9 PATIENT BED TRAY

The baby's bed is polycarbonate made. ***OGB Poly Care 4*** is equipped with Smooth-Tilt, a new bed positioning system which allows the continuous and smooth adjustment of the posture bed in the Trendelemburg and Fowler positions turning the knobs placed on both the left and the right side.

5. ROUTINE MAINTENANCE

5.1. MICROFILTER

The micro-filter should have a filtering capacity not lower than 0.5 μm.
The micro-filter should be replaced for every new patient and checked on routine basis.
Do not attempt to clean, wash or sterilise the micro-filter to use it again.

WARNING

A dirty micro-filter may:

- contaminate the air circulating in the hood
- obstruct the air intake
- affect oxygen concentration
- cause carbon dioxide built-up

Before installing a new filter, clean the micro-filter chamber.

5.2 CLEANING AND STERILISATION

All the components of the ***OGB Poly CARE 4*** can be easily disassembled, without additional tools, for cleaning and maintenance.
GINEVRI cleaning detergent (p/n 1711) may be used for cleaning of any component.
The special alkaline and soluble solution avoids calcareous depositing.
It does not corrode metals and plastic materials.
The special detergent substance is not harmful for the operator.
Don't use abrasive or highly alkaline cleaners.
Never scrape the sheet with squeegees, razor blades or other sharp instruments.
Don't clean the incubator when it is still hot

5.3 DISASSEMBLY

Open front door and lift out the bed tray.
The hood can be removed from the incubator body loosening the retaining screws which hold the bed spacers.
Remove the bed spacers from the hood and remove the hood from the body by lifting it up as shown at page 12.
Place the hood on a flat surface.

5.4 DUSTING

Dust the hood with a clean and soft cloth or paper towel.

5.5 WASHING

After removing all solid wastes and contaminants from the disassembled parts, use a disinfectant-detergent and hot water to thoroughly clean all surfaces with a clean soft cloth, sponge or paper towel. Make sure to clean all holes, baffles, access doors, hand doors etc.
The base, the hood, the water tank, the bed tray, the baffles etc. can be autoclaved (Max 100°C) since they are made of polycarbonate.

5.6 DRYING

Dry the washed surfaces using a clean dump cloth.
Do not use a dry or rough cloth not to scratch the surfaces..

5.7 HEATING UNIT

Disconnect the power supply from the heating unit before cleaning.
Remove the heating unit loosening the 4 nuts. The front panel can be cleaned with a damp cloth and cleaning agent.
The heating element can be dipped in a liquid sterilisation agent. Care must be taken to prevent liquids from coming in contact with electrical parts of the unit.

WARNING

Withdraw the control panel from the base carefully when the heating unit may be still hot. Avoid removing it or touching the heater until the unit has been switched off for at least 30 minutes.

6 - WASHING

REBRIL

Soluble detergent to thoroughly clean and disinfect electromedical equipment and components (p/n 1711).

- It is a cleaning powder, slightly alkaline, easily soluble in water.
- Composition: Active Chlorine 2,4 g., Silicates-Carbonates-Polyphosphates 96 g., Sodium Alkyl Sulfates 1,8 g.
- It is provided with D.L.G. Quality Mark and complies with cleaning and disinfecting precautions for various application and in the food industry.
- It combines a double action both detergent and chlorine active.
- It does not corrode metals, plastic materials and rubber.
- The solution is not harmful for the operator.
- It softens the water and prevents calcareous deposits on the treated surfaces or components.

CLEANING INSTRUCTIONS

- Dissolve the required quantity of powder in enough water (Ratio: 50 gr./10 Lt). Water temperature should be not higher than 25 °C.
- After removing all solid wastes and contaminants disassemble all the parts that are meant to be cleaned.
- Wash them with cold water first.
- Thoroughly clean all the parts and surfaces using the disinfecting solution previously obtained and by means of a clean soft cloth, sponge or paper towel . The more cleaning will be accurate, the more the double action of the disinfectant will be effective.
- Thoroughly rinse all the parts with cold water.
- Dry with a soft cloth

6.1. WARNING

Other cleansers may be used.

Be aware that the use of abrasive or highly alkaline cleaners or solutions containing surface-active agents, chloroxedin, lauril oxide or similar cleaners normally used for hand disinfection may permanently damage Polycarbonate (Lexan) surfaces and eventually be toxic for the patients.

It is advisable to use only cleansers compatible with Polycarbonate (Lexan).

7. TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	REMEDY
- No power , POWER FAILURE Alarm is not activated.	- POWER switch not on.	- Depress POWER switch .
- POWER FAILURE alarm activated.	- Fuse failure. - Power cord unplugged.	- Replace fuse. - Verify power cord is correctly plugged in.
- MAX TEMP activated.	- External source of heating.	- Eliminate external source of heating
- FAN FAILURE activated.	- Dirty fan failure sensor. - Obstructed air circulation system. - Fan motor failure.	- Clean the sensor with a soft clouth. - Remove obstruction. - Replace fan a/or motor.
- LOW TEMP alarm activated.	- Door(s) left open. - Skin probe not properly secured to skin (Skin Mode operation only).	- Close all doors. - Check Skin Probe positioning.
- SKIN PROBE alarm activated.	- Skin probe plug not properly connected. - Probes unit plug not properly connected	- Verify skin probe plug connection. - Verify probe plug connection.
- MAX ALARM + AIR PROBE + SKIN PROBE + HUM PROBE alrms activated simultaneously.	- Tubing not properly installed.	- Check installation.
- Low % humidity.	- Low level of water in the water tank.	- Check water level.
- Low % oxygen.	- Oxygen probe plug not properly connected.	- Verify probe plug connection.
- OXYEN PROBE.	- Oxygen sensor exhausted.	- Replace the oxygen sensor.

WARNING

Withdraw the control panel from the base carefully when the heating unit may be still hot. Avoid removing it or touching the heater until the unit has been switched off for at least 30 minutes.

8. TECHNICAL DATA SHEET

- **BODY**	One piece injection moulded polycarbonate
- **POWER SORCE**	220V 50/60 HZ
- **POWER CONSUMPTION**	440W (540W With Hot Spot)
- **SAFETY CLASS (IEC 601.1/CEI 62.5)**	1st
- **CATEGORY (IEC 601.1/CEI 62.5)**	B
- **MEDICAL DEVICE (93/42/CEE) CLASS**	II B
- **GROUND LEAKAGE CURRENT**	70 μA
- **PROTECTION**	2 Fuses 5x20 mm 2 Amp F (3.15Amp F)
- **POWER FAILURE ALARM**	Included
- **POWER FAILURE ALARM BATTERY**	Included
- **AIR TEMPERATURE INDICATOR**	0.1°C Resolution, 0.6°C Max Error
- **SKIN TEMPERATURE INDICATOR**	0.1°C Resolution, 0.3°C Max Error
- **O2 CONCENTRATION INDICATOR**	1% RES
- **O2 CONC. HIGH/LOW ALARM INDICATOR**	1% RES
- **RH INDICATOR**	1% RES, 10% MAX ERROR
- **AUTOMATIC TEMP. ADJUSTMENT WITH PROPORTIONAL HEATING**	20°C to 38°C
- **MAX TEMPERATURE ALARM**	Audio-visual alarm stops heating Automatically at 38°C or 39°C
- **HUMIDITY CONTROL**	50% to 90%
- **IDEAL ROOM TEMPERATURE**	21°C to 26°C
- **HUMIDITY RANGE OF THE ENVIRONM.**	35% to 90%
- **STORING TEMPERATURE**	-10°C TO +50°C
- **NOISE LEVEL INSIDE THE HOOD**	Lower than 45 – 47dB
- **VENTILATION**	36 Lt. Minute multi-direction
- **MAXIMUM CO2 CONCENTRATION (MEASURED UNDER IEC 6012 – 19 TEST CONDITIONS)**	<0.5%
- **MAX WEIGHT FOR THE BED TRAY**	10 Kg.
- **DIMENSION:**	
- **INCUBATOR**	66x80x70 mm
- **CABINET**	62x80x67 mm
- **WEIGHT :**	
- **INCUBATOR**	32 kg
- **OPEN CABINET**	37 kg
- **CLOSED CABINET**	45 kg
- **ADJUSTABLE HEIGHT CABINET**	51 kg

OGB POLY CARE 4 COMPLIES WITH THE FOLLOWING REGULATIONS

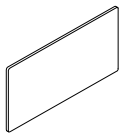
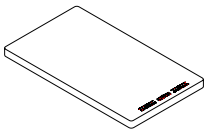
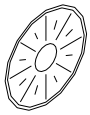
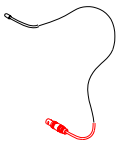
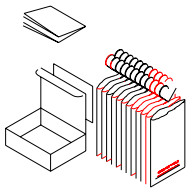
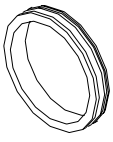
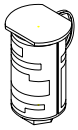
IEC	601.1	(CEI 62.5)
IEC	601.2.19	
EN	55011	
EN	61000-4-2	
EN	61000-4-3	
EN	61000-4-4	
EN	61000-4-5	
EN	61000-4-11	

MEDICAL DEVICE 93/42/CEE
CLASS IIb

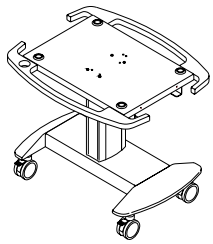
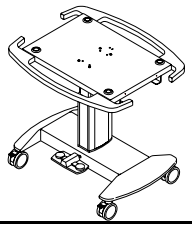
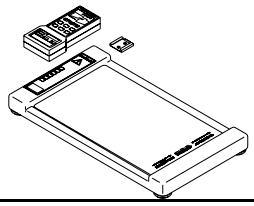
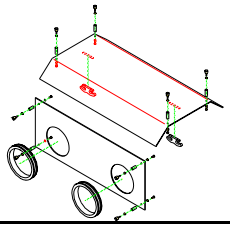
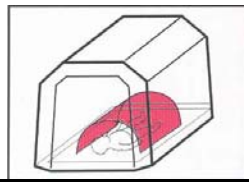
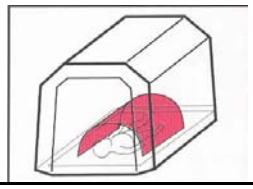
UNI EN ISO 9000:2000 – CERTIFIED QUALITY SYSTEM BY IQNET – No. CERT –IT-37100
UNI CEI ISO 13485 – PARTICULAR REQUIREMENTS FOR MEDICAL DEVICES

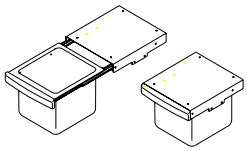
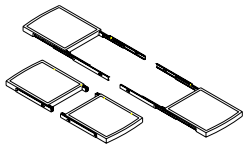
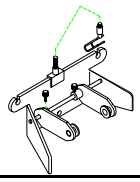
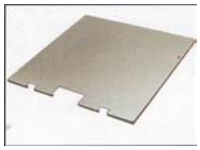
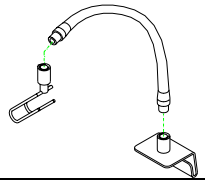
CE 0051

9 SPARE PARTS

Ref.	Code	Description/Image		Quantity
1	11130A72	AIR FILTER		Pack of 12
2	434	MATTRESS		Heach
3	11725A73	SLEEVE		Pack of 12
4	11461A72	THERMOMETRICAL PROBE		Heach
5	565	REFLECTORS GEL REFLECT		Pack of 24
6	1711A	DETERGENT REBRIL POWDER (Pack of 2 Kg.)		Heach
7	11721A73	FLANGE DOOR		Pack of 6
8	12029A73	FLANGE GASKET		Pack of 6
9	10267A73	OXYGEN SENSOR		Heath

10. ACCESSORIES

Ref.	Code	Description/Image	
1	11400A70	CENTRAL AXIS TROLLEY FIXED HEIGHT	
2	11410A70	CENTRAL AXIS TROLLEY ADJUSTABLE HEIGHT	
3	8040	ELECTRONIC SCALE "BILLA"	
4	12058A70	DOUBLE WALL WITH OVAL PORT HOLES	
5	7533	HOT SPOT	
6	559	MICROCLIMATE HOOD 30X20X13	
7	589	MICROCLIMATE HOOD 35X25X15	
8	1521	I.V. POLE ASSEMBLY	

9	**6922**	**I.V. POLE STANDARD**	
10	**110**	**MECHANIC SCALE**	
11	**722**	**PATIENT'S BED**	
12	**11401A70**	**DRAWER**	
13	**11405A70**	**PLANE**	
14	**7647**	**BABY HEAD IMMOBILIZER**	
15	**1693**	**X-RAY FILM PLATE**	
16	**5740**	**PIVOTING SHELF**	
17	**10712A70**	**VENTILATOR HOSE HOLDER**	

11 CERTIFICATE QUALITY SYSTEM GINEVRI S.R.L.

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CERTIFICATO N.
CERTIFICATE N. **9124.GIN2**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

GINEVRI SRL

VIA GIACOMO BONI, 15 - 00162 ROMA (RM)

UNITA' OPERATIVE
OPERATIVE UNITS

VIA CANCELLIERA 25/D - 00040 CECCHINA STAZIONE (RM)

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

EN 46001
ISO 13485:1996

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, installazione e manutenzione di apparecchiature elettromedicali per assistenza neonatale e pediatrica
Design, manufacture, installation and maintenance of electromedical equipment for neonatal and pediatric care

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI QUALITA' E DI GESTIONE DELLE AZIENDE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF COMPANY QUALITY AND MANAGEMENT SYSTEMS

PRIMA EMISSIONE
FIRST ISSUE
2004-04-23

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SINCERT EA: 19

Membro degli Accordi di Mutuo Riconoscimento EA e IAF
Signatory of EA and IAF Mutual Recognition Agreement

La validità del presente certificato è subordinata a sorveglianza annuale e al riesame completo del Sistema di Qualità con periodicità triennale secondo le procedure dell'IMQ

The validity of the certificate is submitted to annual audit and a reassessment of the entire Quality System within three years according to IMQ rules